



12

EUROPEAN PATENT APPLICATION

21 Application number: 89302681.5

51 Int. Cl. 5: A61M 5/14

22 Date of filing: 17.03.89

The title of the invention has been amended
(Guidelines for Examination in the EPO, A-III,
7.3).

43 Date of publication of application:
19.09.90 Bulletin 90/38

84 Designated Contracting States:
AT BE CH DE ES FR GB GR IT LI LU NL SE

71 Applicant: SHILEY INFUSAID INC.
1400 Providence Highway
Norwood Massachusetts 02062(US)

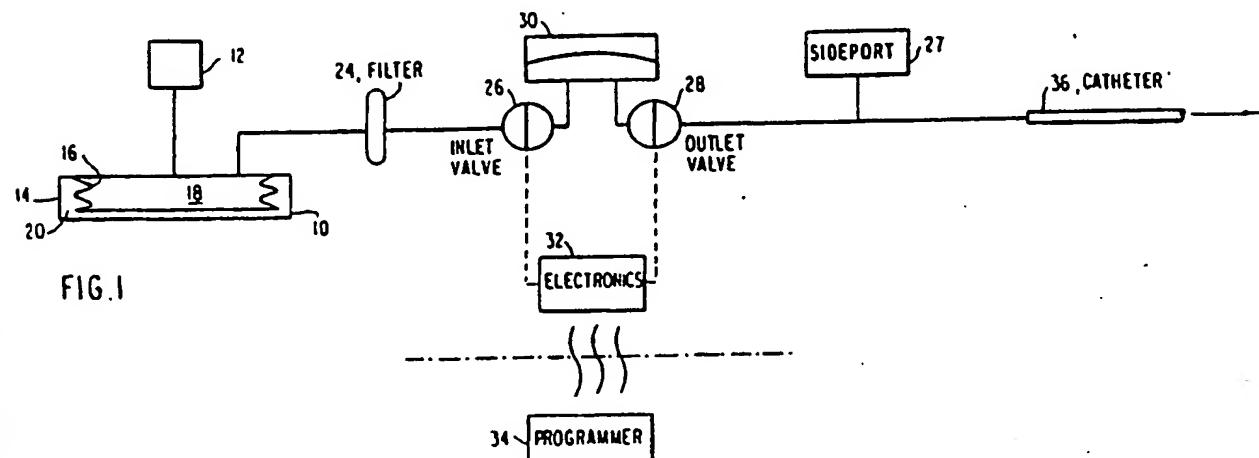
72 Inventor: Idriss, Samir F.
16 Freeland Street
Mattapan Massachusetts(US)

74 Representative: Moore, James William, Dr. et al
Pfizer Limited Ramsgate Road
Sandwich Kent CT13 9NJ(GB)

54 Implantable infusion device.

57 An implantable valve accumulator pump comprises a drug reservoir (18) maintained at constant pressure vapor. The medication metering assembly comprises a fixed volume accumulator (30) positioned between a pair of valves (26,28). The valves alternately open and close to admit medication from the reservoir into the accumulator and to dispense a

precise volume spike to an outlet catheter (36). In order to minimize dead volume and insure complete discharge, the accumulator employs a titanium diaphragm (90) seated in one position by a recessed stop and in the discharge position by a spacer plate (98) having a grooved pattern. The unit is externally programmed.



EP 0 387 439 A1

PROGRAMMABLE VALVE PUMP

This invention relates to an implantable infusion pump for the dispensing of infusate. In particular, it relates to a pump operating at positive pressure which is programmable to dispense medication in accordance with different specified flow rates.

Implantable infusion pumps are currently used for a variety of medical purposes. Typical of such commercially acceptable devices are the INFUSAID Model 100 and 400 devices. Such devices are implantable in the human body and rely on a liquid/vapor equilibrium to maintain constant pressure on the drug which is housed therein so that the drug flows through a capillary in order to maintain a constant flow rate. Such devices are characterized by "constant flow" and are used in a variety of medical applications, for example, to dispense chemotherapy at a relatively constant flow rate. As background to the INFUSAID Model 100 and 400 devices, are U.S. Patents 3,731,681 and 4,496,343.

There are a variety of medical conditions where a patient requires an adjustment in the dosage and as such, constant flow pumps are inadequate. A typical example is diabetes where the quantity of medication, such as insulin, to be infused varies due to requirements of the patient. Fluctuations can occur on a daily basis or more randomly as a function of the ingestion of food. It is known that the amount of medication to be infused per unit of time should be adjusted at certain time intervals. A patient's requirements may fluctuate at either set, known rates or vary abnormally, for example, by the ingestion of food or other transitory conditions. Those conditions require the administration of a bolus dose of infusate. The daily administration of insulin requires a basal dose that is supplanted by bolus doses, for example, at meal times. The difference in flow rates between the basal and bolus doses may be quite large, the bolus dose several orders of magnitude larger than the basal dose. Consequently, to achieve proper flow rates over the spectrum of desired rates, such a device must have the ability to continually infuse at very low rates yet provide, periodically a substantially increased flow rate.

Within the reported literature, a number of implantable programmable concepts have been disclosed. Typical are U.S. Patents 3,894,538; 4,077,405; and 4,443,218. A category of programmable pumps is so-called negative pressure pumps typified by U.S. Patents 4,482,346 and 4,486,190. These devices are solenoid activated negative pressure devices. In those systems a diaphragm storage chamber maintains the drug to be infused. A diaphragm separates the drug from pro-

pellant, normally Freon maintained at negative pressure. The solenoid is activated driving an armature and a bellows pumping element. The displacement of the armature opens a check valve which draws drug from the storage chamber into a downstream pumping chamber. A restriction is used to prevent backflow in the outlet during this short period. When the pump chamber is full, the check valve closes and the solenoid is deenergized. A spring force is used to displace the bellows into the chamber thereby pumping the drug through a restrictor and into the patient. The bellows armature assembly comes to rest on the check valve to insure that no backflow occurs during the rest period. Such a system operates at negative pressure to insure no forward flow during this rest period, that is the drug chamber pressure is below body pressure.

Such negative pressure systems suffer from several significant disadvantages. First, the ingestion of air into the system will stop the drug flow process. Consequently, such devices require expensive fill and empty systems for recycling of the implantable device. A more practical and serious problem is that special handling is required for the devices themselves. The drugs used with such devices must be vacuum conditioned thereby requiring that special steps be taken by those who in many cases are medical technicians and are technically unsophisticated. The drugs must also be packaged and shipped with special care to maintain such vacuum conditioning. Consequently, these devices, while offering theoretical advantages, in practice suffer from significant disadvantages.

A second class of device is the so-called positive pressure pumps which are used in combination with an accumulator pump. Typical are U.S. Patents 4,221,219; 4,299,220; and 4,447,224. Such devices operate at positive pressure thereby eliminating the problems of prior art negative pressure devices. Because the drug chamber is maintained above body pressure, there is, however, a remote potential for an overdose of drug should all the valves in-line with the output fall open at the same time. An extremely high degree of safety, however, may be achieved in such systems by the use of redundant or fail-safe valves together with the addition of sensor/shut-down circuits. Such, however, results in significant cost increases which are added to the system.

Reference is made to U.S. Patent 4,525,165. This patent employs a series of pump and accumulator elements between the drug chamber and the outlet. Medication is drawn out of the chamber

by a pump and delivered to a bellows accumulator. This system is not only complex but cannot accurately meter doses given the variable volume of the bellows.

To deal with these situations where deficiencies exist within prior art devices, U.S. Patent Application S.N. 824,986, commonly assigned, deals specifically with a programmable positive displacement system having a pumping chamber which is placed in the path of fluid communication between the pressurized drug reservoir and a flow restrictor. By use of external programming, the device can be used to expel infusate from the pumping chamber at varying rates. While such systems provide advantages over the prior art, a need exists to define a system which is simple in operation yet provides the ability to accurately meter dosage. System simplification by the elimination of bellows chambers, implantable solenoids and the like with their attendant power requirements, represent a standing requirement for reliability and ease of operation of such implantable devices.

While not implantable devices, there exists in separate art, techniques for dispensing fluids by intravenous administration. Representative are U.S. Patents 4,121,584; 4,261,356 and 4,262,824. These devices employ a valved accumulator metering system from a hydrostatic source using a gravity feed. The problems inherent in implantable technology are not recognized or addressed. There is similarity in the concept of using a metering chamber that is valved as in the case of the 219 patent with a diaphragm, but the application to implantable devices is not stated or recognized in the industry.

Given these recognized shortcomings in the prior art, it is an object of this invention to provide a positive pressure programmable valve pump that is implantable into a living body. It is a further object of this invention to define a system which utilizes a valved accumulator device to precisely deliver small quantities of a drug at programmed rates. Consequently, reliability and simplicity of the system is a primary aspect of this invention.

It is a further object of this invention to define a device which operates at positive pressure thereby removing the problems of handling and potential failure modes which are inherent in negative pressure systems.

This invention comprises four essential components. The first is a rechargeable, constant pressure drug reservoir in series with a bacteria/air-filter. The second major assembly is an electronically controlled metering assembly comprising two normally closed valves adjacent and opposite to a fixed volume accumulator. The third fundamental concept used in the system is an outlet catheter. These three components comprise the implantable aspect of the pump. The fourth aspect of this

invention is the external programmer.

In accordance with this invention, initial "pumping" is provided by the reservoir which is used to fill the accumulator to its fixed volume. The accumulator is then "dumped" via the discharge catheter to the desired infusion site. In accordance with this invention, a pressure which is intermediate between the reservoir and the outlet is maintained behind the accumulator so that it fills and empties completely and rapidly. The accumulator is alternately filled and emptied by the alternate switching of the valves. The rate of switching therefore governs the rate of pumping and thus the delivery rate.

Valve control is provided in the implantable pump by means of an on-board processing system and power supply. The processor is externally accessed through a telemetry link which can be used to both program the pump operation and obtain diagnostic information as to the operation of the device.

In accordance with basic implantable pump technology, the pump reservoir may be refilled periodically and can be accessed transcutaneously by means of the reservoir septum. That is, in accordance with known techniques, a stressed elastomeric seal may be punctured with a specially shaped needle. The septum is self healing for a defined number of punctures. Reservoir pressure is provided by a moderately high vapor pressure fluid in a two-phase equilibrium. Such is known in the context of existing constant flow implantable devices. Pressure is recharged at each refill since the vapor is recondensed.

Fig. 1 is a schematic diagram showing the complete system and a schematic diagram of the flow;

Fig. 2A is a schematic diagram illustrating the pumping cycle of the accumulator;

Fig. 2B is a time-flow rate chart of the delivery schedule of the system;

Fig. 3 is a cutaway side elevation of the basic construction of the implantable pump portion of the system;

Fig. 4 is a cutaway schematic view of the valve/accumulator metering system in accordance with this invention;

Figs. 5A and 5B are side and top views of the accumulator and in Fig. 5B a top view of the spacer plate component of the accumulator; and

Fig. 6 is a cutaway side view of the switch accumulator.

Referring now to Fig. 1, schematic diagram of the essential aspects of this invention is depicted. The invention is a positive pressure programmable valve pump comprising a constant pressure drug reservoir 10 which is refillable by means of a septum 12. Such devices are known, for example, the INFUSAID Model 100 and 400 devices. Those

systems comprise a sealed housing 14 containing a bellows element 16 having a chamber 18 comprising the drug reservoir. The bellows 16 separates the housing into a second zone 20 normally filled with a two-phase fluid which has a significant vapor pressure at body temperature. Thus, as the fluid vaporizes, it compresses the bellows 16 and urges the contents of the reservoir 18 through an outlet leading to an infusion site. During the process of refilling, the chamber 18 via the septum 12, the two-phase fluid is pressurized condensing a portion of the vapor and returning it to its liquid phase. As indicated, such basic constant pressure devices are known in the art as described in U.S. Patents 3,731,681 and 4,221,219.

Typically, the reservoir 18 has a volume of approximately 25ml and the pressurization maintained in the system is approximately 23.2psia. A sideport 27 can be used for direct bolus injections. Sideports are used in the INFUSAID Model 400 and described in U.S. Patent 4,496,343.

An outlet 22, from the reservoir 18 delivers infusate from the reservoir via a bacterial filter 24 to the electronically controlled metering assembly.

In accordance with this invention, the metering assembly comprises two normally closed valves 26, 28, which are positioned on the inlet and outlet sides of an accumulator 30. The accumulator operates at a constant volume, very low, in the range of 1 μ l pressurized typically to 19.2psia. The valves 26 and 28 are controlled electronically via a module 32 which is programmed utilizing an external programmer 34. Fig. 1 illustrates in a chain line, the pump envelope which separates the electronics 32, that is the system which is implanted, from the external programmer 34. The programmer can employ known technology for example that disclosed in the above co-pending application which is incorporated herein by reference.

The programmer 34 is a hand held unit using a touch screen. It provides a data transfer link to the electronics 32 implanted as a part of the device (see Fig. 3). In a memory, the programmer 34 maintains a patient history based on storage of real time data. Data as to device status, such as battery condition, diagnostics on valve current, prescription in use and the like are retained. The external programmer also has different interrogation modes such as initial calibration and protected modes for technician use.

The outlet from the accumulator 30 is via a catheter 36 which delivers the infusate to the site in the body to which drug delivery is required. As indicated by the arrow in Fig. 1, the delivery of infusate occurs at the infusion site below the accumulator pressure forcing discharge through the catheter. This pressure may be atmospheric (typically 14.7psia) or cardiovascular pressures

slightly above atmospheric, e.g. 17.6psia arterial.

Referring now to Fig. 2A, the pumping cycle is schematically illustrated. The salient aspects of this section of the system comprise the valves 26, 28 and the accumulator 30. The first step is one where both valves 26 and 28 are closed and the accumulator 30 is empty. Infusate is delivered from the reservoir 18 through conduit 22 and filter 24 to fill the accumulator 30. Thus, as a second step in the operation the valve 26 is opened while valve 28 is closed to fill the accumulator to its fixed volume. The third step is then to close both valves 26 and 28 with the accumulator now full. The final step in the accumulator cycle is the opening of valve 28 while valve 26 remains closed to empty the accumulator through the catheter 36. Consequently, the accumulator is alternately filled and emptied by the switching action of the valves. A pressure intermediate between that of the reservoir and the outlet is maintained behind the accumulator so that it fills and empties completely and rapidly. The rate of switching of the valves therefore governs the rate of pumping and accordingly determines the delivery rate of infusate.

Referring to Fig. 2B an example of the delivery rate of this system is illustrated. Fig. 2B is a chart plotting a flow rate in the y-axis against time in the x-axis. The output of the pump is periodic and is a function of the frequency of the valve cycle. Thus, the faster the valve cycle, the greater the number of accumulator discharges per unit time. Each discharge is in the form of a volume spike.

In Fig. 2B a change from a basal rate to a desired bolus rate, that is an increase in flow rate above the basal rate, is illustrated by means of the square wave on the left-hand portion of the time chart. This would be the programmed bolus flow into the electronics package 32. The pump, to establish the required bolus flow rate, would increase the frequency of the discharge spikes by varying its pump cycle during the bolus period as illustrated in the center of Fig. 2B. The total number of spikes are integrated over time so that the flow rate volume replicates that required by the desired bolus flow rate. The output through the catheter 36 to the bloodstream is illustrated in the right-hand portion of Fig. 2B.

By integrating the volume of the pump over time, given the number of pump cycles, and the volume of each discharge, digital basal and bolus rates closely replicating the required values, that is flow rates having the required amplitude over the required time, are delivered. With sufficiently chosen accumulator volume, drug concentration and discharge rate, the delivery site can filter the output to achieve a desired "continuous" and basal dosage.

Referring now to Fig. 3, the implantable portion

of the system is illustrated in cross section. The implantable portion of the reservoir system 10 comprises a housing 14 having therein all of the essential elements comprising the reservoir 18, the Freon two-phase pressurizing chamber 20, the electronics module in location 32, and the accumulator valve aspects of the system housed in location 33. The pump reservoir 18 is periodically accessed transcutaneously via the reservoir septum 12. The septum is a stressed elastomer seal which may be punctured with a specifically shaped needle. It is self-sealing for a finite number of punctures. As in the case of known systems, reservoir pressure is provided by a moderately high vapor pressure fluid maintained in a two-phase equilibrium. Freon is, as mentioned, a typical material. Pressure in the system is recharged with each refill since the Freon vapor is recondensed.

As illustrated in Fig. 3, the mechanical construction of the device comprises a hollow disk-shaped housing generally made of two components. That is, the housing 14 comprises a lower section 40 and an upper or cover section 42. The two main cavities of the system are separated by a solid base plate 44 which defines the central core of the unit. The lower cavity is subdivided into two chambers 18 and 20 by means of the bellows 16. Chamber 18 contains the drug while Chamber 20 contains the Freon pressurization system. During manufacture, a relatively small amount of the volatile fluid, typically Freon, is injected into the region 20 via a small fill tube not illustrated. The Freon then comes to a two-phase equilibrium within this chamber. The vapor pressure is determined by the equilibrium pressure and remains constant for constant pump temperature and quasi-static volume changes of the bellows 16. The magnitude of the storage reservoir pressure is then the sum of this vapor pressure and the mechanical pressure which is associated with the spring rate of the bellows 16.

The central core region contains the needle piercing septum through which drug is injected into the chamber 18. The septum includes a needle-stop 46. The needle-stop is a non-metallic cup which is used to support the needle and limit its travel yet at the same time prevent damage to the needle tip. When the needle is removed, drug is sealed in the reservoir 18.

Thus, the needle, not illustrated, punctures the septum 12 and comes to rest on the stop 46. Drug is then dispensed into chamber 48 and via flow passages 50, is delivered into the reservoir 18. A check valve 52 may optionally be used in the inlet. Thus, as illustrated by the flow arrows in Fig. 3, drug delivered into the chamber 48 passes through the through-holes 50 and, if in place, the increased pressure of the fluid or the force of the needle pushing down on the needle stop 46 opens the

check valve 52 to deliver drug into the chamber 18.

The system includes within the housing 14, the electronics cavity 32 containing the necessary microprocessor electronics and battery. Battery life is sufficient to power the device during its normal intended implantable life. The housing 14 includes within the central core region the two valves 26 and 28 and the accumulator 30. The valves 26 and 28 comprise two miniature solenoid valves which are intimately connected to the accumulator 30. The valves 26 and 28, to be discussed herein are manufactured by Wilson Greatbatch Company and illustrated in detail in Fig. 4. It is to be understood that such valves are commercially available. The valves hermetically isolate the fluid sides of the valve from the electrical side of the valve.

Fig. 3 illustrates by arrows the flow configuration from the chamber 18 to the outlet catheter 36. The drug, from chamber 18, passes through circular openings 54 through the annular filter assembly 56. The filter 56 is interposed between the base plate 44 and a backing plate 57 and is sealed at its radially inward and outward points by means of annular seals 60 and 62. The drug then passing through the filter 56 is subject to valve action by valve 26 filling the accumulator 30 and then dumped via valve 28 into the outlet port 64. A right angle connector 66, locked into the outlet port and sealed via O-rings 68 and 70, couples the housing 14 to the catheter 36.

Referring now to Fig. 4, the details of the valve/accumulator metering assembly are depicted. Valves 26 and 28 are miniature solenoid valves attached to the accumulator 30 by means of a weld point 72. Valves are disposed in a side-by-side arrangement having a solenoid assemblies 74 and applicable input power via leads 76. The valves are operably powered to drive a working plunger 78 biased by means of spring 80. The working plunger and return spring assembly are isolated from the solenoids by means of an isolation diaphragm 82. This isolation diaphragm is a welded metal diaphragm sandwiched between both sides, that is the electrical side and the fluid side of the system. The diaphragm 82 does not transmit pressure to the working plunger 78 therefore the only pressure differential which opposed valve motion is that which is across the valve seat area.

The flow path is illustrated by the arrows in Fig. 4. At the input conduit 54, the nominal pressure of the infusate is 23.2psia. With valve 26 in the open position, drug is delivered upward through the valve seat 84 (shown closed in Fig. 4), into the accumulator flow passage 86. As can be seen from Fig. 4, the configuration minimizes the total volume and any possible stagnant flow passages which exist between the valve seats. The area between the valve seats comprises the accumulator storage

space. Consequently, to minimize entrapped air, a low "dead volume" is designed into the system. Dead volume is the non-compliant volume between the valve seats, that is the area between seats which defines the accumulator flow passage 86 and the non-compliant portion of the accumulator chamber 102. The valve seats are illustrated at the points 84. The dead volume between the valve seats 84 (not including the compliant accumulator volume which is nominally 1 μ l) is in the range of 4.9 - 8.4 μ l. When closed, the accumulator 30 is isolated. When opened, the valves allow fluid communication to be established between the accumulator and the inlet conduit 54 or the outlet conduit 55.

Referring now to Figs. 5A and 5B, details of the accumulator are depicted. The accumulator comprises a diaphragm 90, a backing plate 92, an end cap 94, a fill tube 96, and a spacer plate 98.

The accumulator and its diaphragm are a key component in this system. The diaphragm 90, as illustrated in Fig. 5B, is a circular disk of a thin metal sheet. Preferably titanium may be used. The disk is selected to have a diameter and thickness of virtually negligible spring rate over the desired range of deflection. Thus, the diaphragm acts as a compliant, flexible wall which separates fluid from the environment behind it.

The upward motion of the diaphragm 90 is limited by the backing plate 92. Backing plate 92 is a metal plug of the same material and diameter as that of the diaphragm 90. It is provided with a shallow concave profile manufactured into its lower surface. This surface 100 acts as a contoured stop for the diaphragm 90. Dimensions of the contour are chosen to match the general profile of the diaphragm 90, when it is deflected by a predetermined fixed volume (e.g. 1 μ l). This predetermined fixed volume is the volume desired to be metered, that is the volume of one discharge spike as illustrated in Fig. 2.

The backing plate 92 acts as a mechanical stop which limits the motion of the diaphragm after the accumulator cavity 102 has been filled to a specified volume. The contour of the plate is designed so that it contacts as much of the surface of the diaphragm when the volume in chamber 102 has been reached. This surface on the backing plate 92 then rigidly stops all portions of the diaphragm from moving and for any further increase in pressure, the volume of the accumulator in zone 102 will not change. As long as the operating pressure of the pump is higher than the pressure required to fill the accumulator (to be discussed herein) the accumulator will then always store, in zone 102, the same volume irrespective of operating pressure variations. The ability to store and discharge the same volume repeatedly over a very

large number of cycles irrespective of pump pressure, represents an important advantage over other implantable pumps in which the discharge rate is a function of the pressure generated by the two-phase fluid. This is because pressure changes associated with two-phase fluid pumps are a function of pump temperature. If the user is in an environment where there is a significant temperature change at skin surface, for example during swimming, the pressure of the device will change.

Pressure differential across the diaphragm 90 determines whether it fills or empties. On the non-fluid side, the pressure effects both the fill and empty differentials. This pressure must be lower than the main reservoir pressure yet higher than the catheter outlet pressure. Consequently, the backfill pressure which exists on the side of the diaphragm 90 opposite that of the accumulator zone 102 must be controlled at a value which allows for complete filling yet guarantees complete emptying of the accumulator for any normal variations in reservoir or outlet pressure. Such a pressure can be chosen and maintained by controlling the pressure in chamber 104 and having it maintained in fluid communication with the backside of the diaphragm 90. The endcap 94 is used to cover this chamber. A fill tube 96 is used to charge the chamber 104 with an inert gas such as Argon maintained at 19.2psia. The volume defined in the chamber 104 is chosen to be large enough so that any variations in the total volume due to diaphragm displacement will have negligible effect on the backfill pressure. Once chamber 104 has been filled with a pressurized gas, the fill tube 96 is sealed by welding. The tube 96 is chosen to have a small inside diameter so that changes in its length during welding or rework will not significantly effect the chamber volume and consequently, the backfill pressure.

Figs. 5A and 5B illustrate the details of the spacer plate 98. The spacer plate performs three major functions. First, it supports the diaphragm 90 during discharge. Secondly, it provides passages as illustrated in Fig. 5B to enhance fluid flow and thirdly it provides a technique for mounting the completed and tested units to the valve subassembly. In the same manner that the backing plate 92 supports the diaphragm during filling of the accumulator chamber 102, the spacer 98 is used to limit diaphragm motion during discharge. The spacer plate, however, need not be contoured because it supports the unstressed, that is the flat position of the diaphragm which is established during welding. The continuous contoured surface desirable to use as a mechanical stop on the gas-filled side of the diaphragm, that is the chamber 104, is undesirable on the fluid side. Intimate contact of two relatively flat surfaces with a liquid

interface will create a suction effect which makes the separation of those surfaces difficult. This suction effect can be overcome by the addition of a checkerboard groove pattern as illustrated in Fig. 5B. A series of orthogonal checkerboard grooves 105 are provided on the surface of the spacer plate 98. Additionally, a circumferential groove 106 is provided to establish fluid communication between the inlet 58 and the outlet 59. Consequently, the spacer plate 98 defines flow paths comprising an annular path along groove 106 and an orthogonal flow path along grooves 105. The grooving is designed to permit complete free flow of fluid underneath the flattened diaphragm. Additionally, the grooves assist in washing of areas which might otherwise remain stagnant. Dimensions of the grooves may be chosen to provide an appreciable surface to support the diaphragm, that is the rectangles 107 between the grooves 105 but maintain the accumulator dead volume at a minimum level. A grooved spacer plate also promotes the rapid filling and emptying of the accumulator zone 102 which in turn minimizes the time and therefore the energy necessary to hold either valve open. It can be appreciated that decreased valve energy requirements in such a system materially increase the life of the pump since the overall energy requirements of the system are decreased.

The bottom of the spacer plate 98 contains two counter bores 58 and 59 to mate with the valves which are illustrated in Fig. 4. The bottom surface 108 of the spacer plate 98 is controlled to be flat and have a smooth surface finish which will mate with the surface of the same quality on the valve subassembly. It is at this point that the weld 72 is made. Such again guarantees a minimum dead volume between parts and the minimum space for air entrapment. The geometry of the outer flange 110 matches the mating plate from the valves and permits a hermetic weld 72 around the rim.

Referring now to Fig. 6, a modified accumulator is depicted. Fig. 6 illustrates a modification which utilizes the same basic elements of the accumulator illustrated in Figs. 5A and 5B but employs an electrical switch to signal the level of volume within the accumulator. This dual function provides an important safety feature which can indicate the presence of leaks in the valve seats and accumulator welds or, sticking of the valves. Because this invention utilizes positive pressure, failure of one or both valve seats will lead to improper dosing of the reservoir contents. A switch accumulator can then be used to sense conditions which are suggestive of valve malfunction and warn the pump to signal operator and discontinue dosing.

The operating principles of the switch accumulator illustrated in Fig. 6 are identical to those of the accumulator illustrated in Figs. 5A and 5B. One

modification, however, is that the contour has been moved to the spacer plate and that the backing plate surface 92 is now manufactured flat. In Fig. 6, those elements which are common to the accumulator design in Fig. 5 are given like identification numbers. The backing plate comprises three elements that are used to electrically isolate the center of the plate from the diaphragm 90 and yet maintain the ability to store a sealed volume of inert gas. In the configuration of Fig. 6, the endcap 94 and fill tube 96 have a dual function, that of chamber cover and electrical lead. The lead 110 is shown schematically attached to a flange 112 forming a portion of the endcap assembly. A ceramic cup 113 is lined with a metal 111 to provide a conductive path between stop 114 and lead 110. The diaphragm is used as a moving switch contact. That is, a full diaphragm will short the lead to ground via the metallized ceramic 111 on the inside of the ceramic cup 113 and conductive stop 114. Thus, a signal is issued indicating that the accumulator is full, diaphragm in the upward position. This signal can be sensed by the electronics just prior to opening or just following the release of either valve. Consequently, by determining conditions during the sense period and by the switch state, a variety of diagnostic determinations can be made.

For example, during a sense period just prior to the inlet opening, if an open switch condition exists, then the system is functioning properly. If, however, the switch state is closed then, it can be determined that there is a leak in the inlet valve 26. During the same period just prior to pulsing the outlet, to release infusate from the accumulator, if an open switch exists, then a leak exists in the outlet valve seat or one of the valve or accumulator welds. If, however, the switch illustrated in Fig. 6 is closed during the outlet sense period, the system is deemed to be functioning properly. In a similar manner, by sensing during the inlet portion of the cycle, but immediately following release, an open condition in the switch will indicate that the inlet did not open or that there is a leak in an accumulator or valve weld. However, sensing the switch state as closed during the same period, deems the system to be working in an acceptable configuration. Thus, by utilizing a switch accumulator, a relatively large amount of information can be obtained about the status of the valve seats or metering system hermeticity. By repeatedly pulsing the valve, the failure mode can be determined to be repeatable or simply artifact.

While not illustrated, it is also possible to have an audiotransducer which will signal the user in the case of failure of one or both of the valves in the pump.

As can be seen by this invention then, a pro-

rammable pump exists which operates at positive pressures and accurately controls the flow rate by metering discrete and repeatable volumes through a microaccumulator. The accumulator is filled and emptied by alternately cycling two control valves which are in series with the accumulator. Thus, by setting the cycling rate of the valves, the pump dispensing rate may be controlled.

The accumulator itself operates at a pressure which is intermediate between the pump reservoir pressure and the outlet pressure. This design pressure, when taken in conjunction with the negligible internal spring rate, guarantees a complete filling and emptying of the system. The volume, however, is repeatedly demonstrated, that is repeatedly dispensed and the valve energy requirements may be minimized. Given the design of the valves themselves, minimum dead volume and flow through occur. This minimizes the danger of entrapped air or stagnant flow in the system.

It is apparent that modifications of this design and of preferred embodiments therein may be made without departing from the essential scope of this invention. Having described my invention, I claim:

Claims

1. An implantable infusion apparatus including a sealed housing (14) having an inlet septum (12), a rechargeable positive pressure infusate reservoir (10) in said housing, characterized in that there is provided metering means in said housing receiving infusate from said reservoir, said metering means comprising first and second valves (26, 28) and a fixed volume accumulator (30) positioned in fluid communication with each of said valves, electronic means (32) in said housing for controlling the operation of said valves, such that when a first of said valves (26) is open, infusate flows from said reservoir into said accumulator to fill said accumulator and when the second valve (28) is open and the first valve closes, infusate flows from said accumulator and an outlet (36) in fluid communication with said metering means to dispense infusate to a site in a living body, whereby infusate dispensed in a series of predetermined volume spikes, the frequency of said spikes determined by the cycling rate of said first and second valves.

2. The device of Claim 1, wherein said first and second valves (26, 28) are positioned side-by-side in fluid isolation with each other, each of said valves having a conduit (86) to said accumulator that may be opened or closed by a valve member (84) and, said accumulator having an inlet (54) aligned with one of said conduits and an outlet (55) aligned with the other of said conduits.

5 The device of Claim 1, wherein said accumulator comprises an end cap (94), a backing plate (92) having a recessed contoured surface (100), an inextensible diaphragm (90), and a spacer plate (98), said diaphragm sandwiched between said backing plate and said spacer plate.

10 4. The device of Claim 3, wherein said backing plate (92) contains a recess (104), and recess covered by said end cap (94), means (96) to fill said recess with a fluid under pressure and conduit means in said backing plate to establish fluid communication between said recess and one side of said diaphragm to bias said diaphragm.

15 5. The device of Claim 3, wherein said contoured surface (100) defines a stop for said diaphragm (90) when said accumulator has been filled with infusate whereby said contoured surface contacting substantially the entire surface of said diaphragm to limit any change in the stored volume of the accumulator irrespective of changes in pressure of infusate delivered from the reservoir to said accumulator.

20 6. The device of Claim 5, wherein said spacer plate (98) comprises a groove pattern (105, 106) confronting said diaphragm (90) to provide fluid flow for complete discharge of infusate from said accumulator.

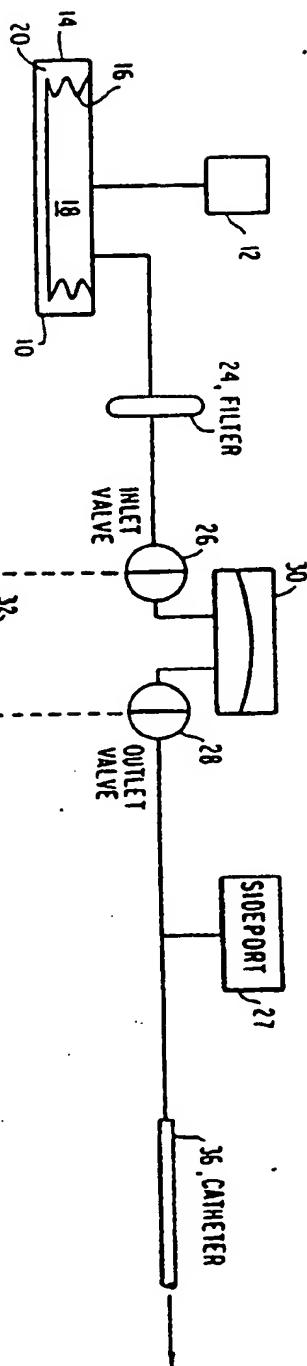
25 7. The device of Claim 6, wherein said spacer plate (98) further comprises inlet (58) and outlet (59) ports, an annular groove (106) between said inlet and outlet and said groove pattern comprises a series of orthogonal grooves (105) surrounded by said annular groove.

30 8. The device of Claim 5, further comprising a conductive stop (114) for said diaphragm, said backing plate (92) comprising a conductively lined (111) ceramic cup (113), and electrical means (110) providing an output to determine the position of said diaphragm.

35 9. The device of Claim 1, further comprising programmer means (34) external to said housing for interrogating and programming said electronic means.

40 10. The device of Claim 1, further comprising an outlet catheter (36) attached to said housing, said outlet catheter including a connector (66) locably insertable into said outlet port.

45 11. The device of Claim 1, further comprising a sideport (27) for the direct injection of a drug into said outlet. 00708



三

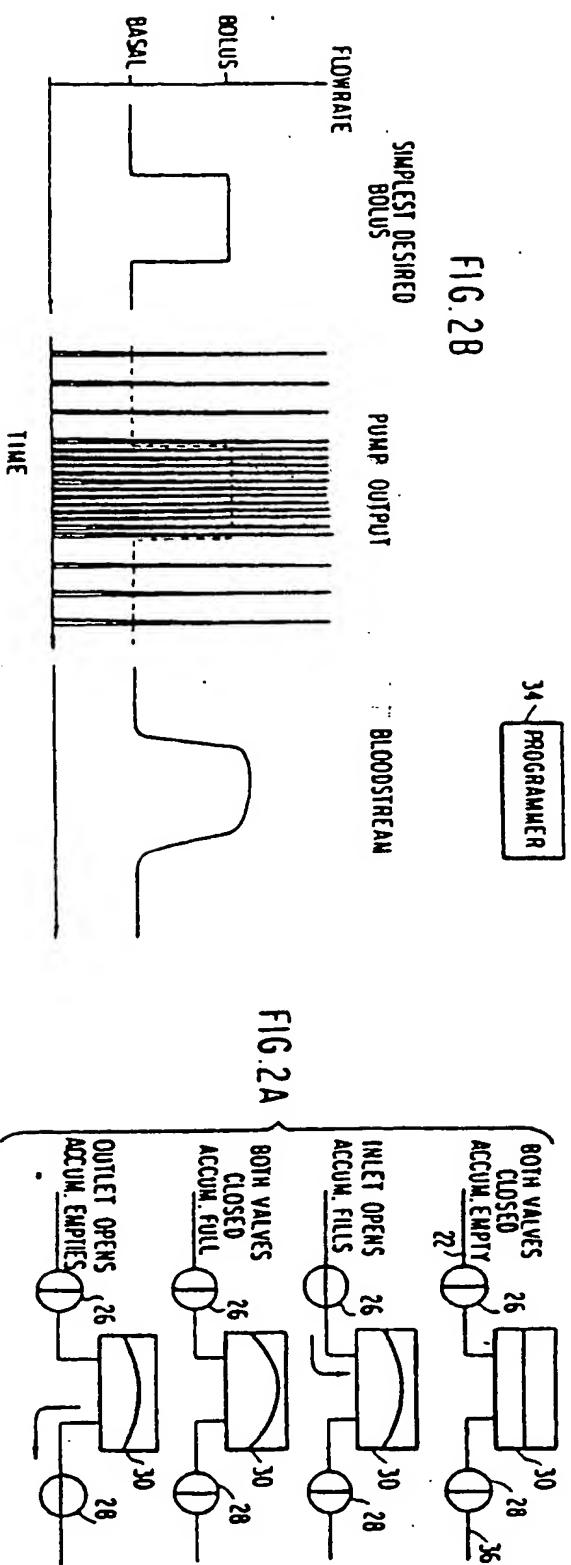


FIG. 2A

FIG. 3

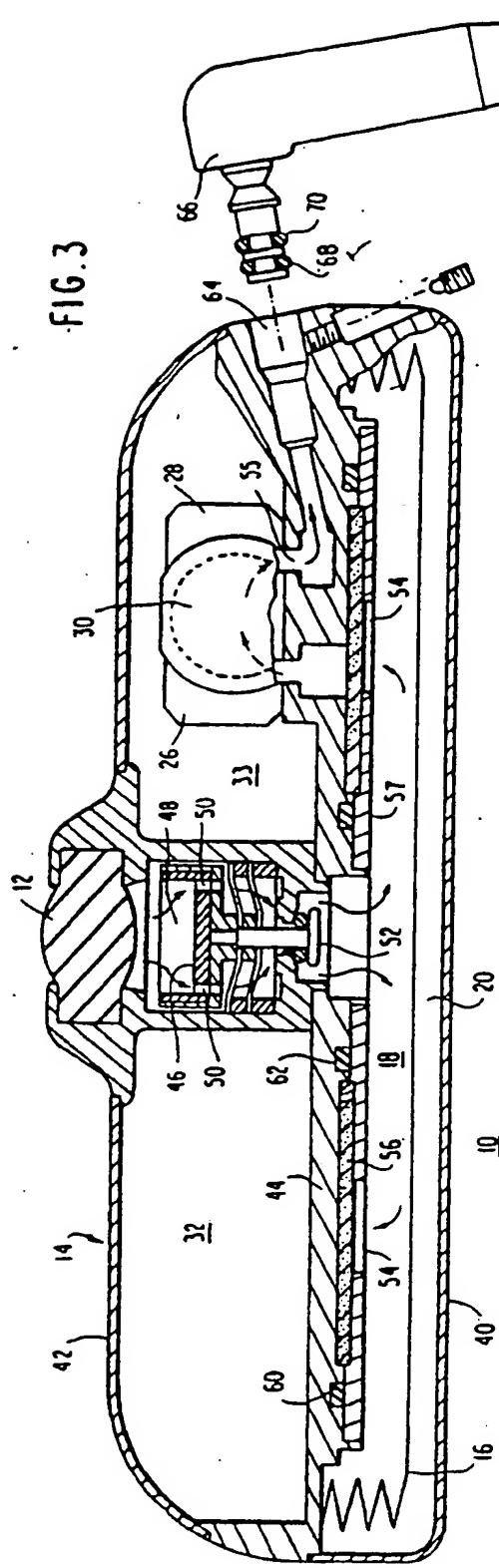


FIG. 5A

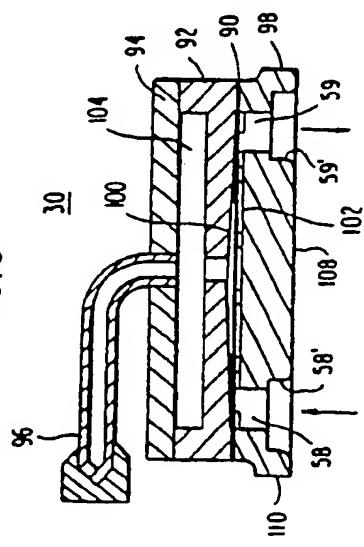


FIG. 5B

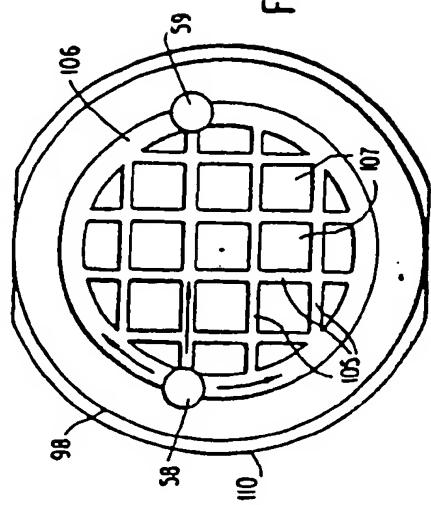


FIG. 4

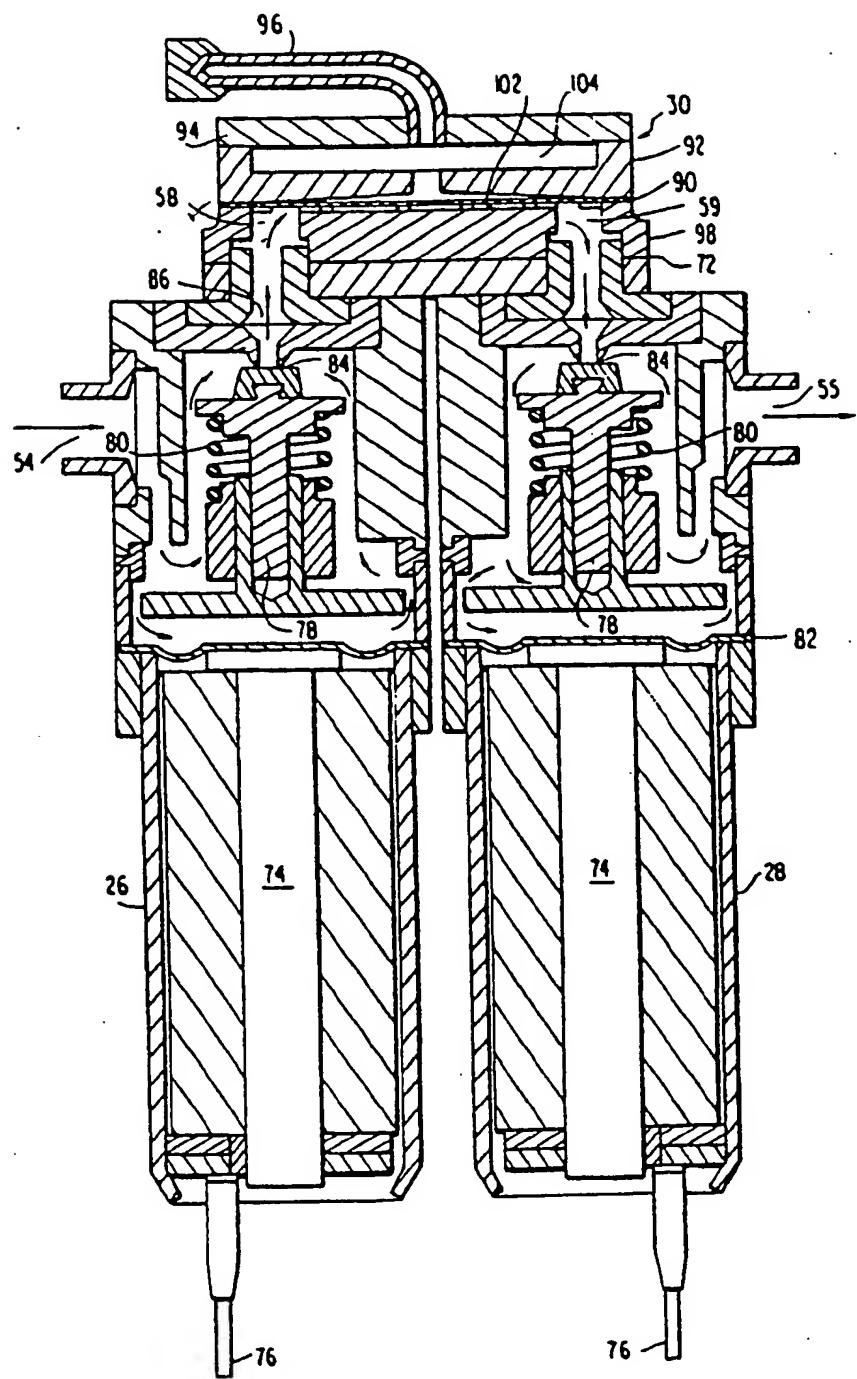
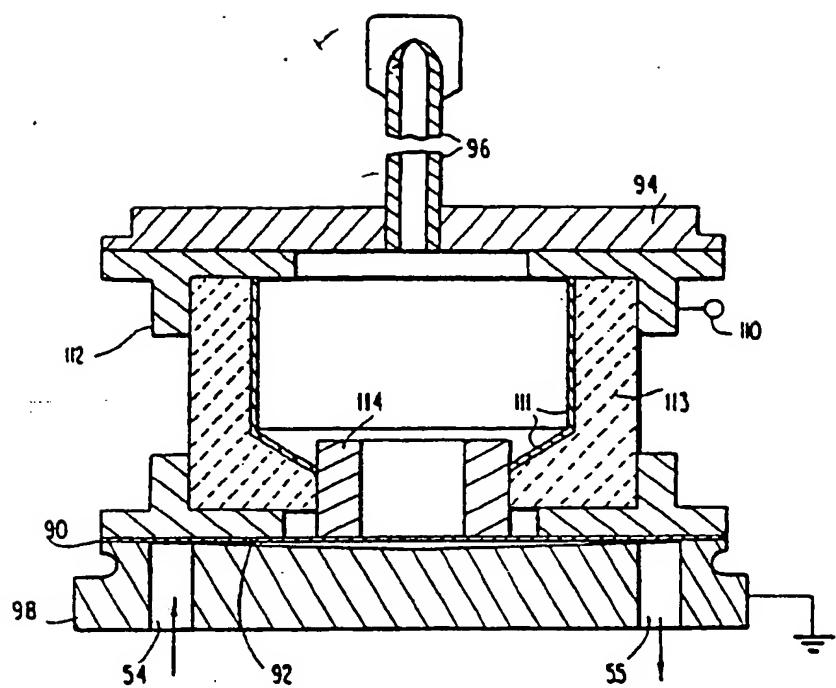


FIG. 6





DOCUMENTS CONSIDERED TO BE RELEVANT					
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)		
X	DE-A-3 520 782 (SIEMENS AG) * Abstract; page 17, line 33 - page 18, line 13; figures 1,4 *	1,2,9	A 61 M 5/14		
Y A	---	3-7,11 8			
X	EP-A-0 183 351 (FEINGOLD) * Page 7, line 36 - page 8, line 12; page 11, line 29 - page 11, line 36; figures 1,2,5,7 *	1,2,9, 10			
A	---	3-8			
Y	FR-A-2 417 299 (BAXTER TRAVENOL) * Page 22, line 13 - page 22, line 29; figures *	3-7			
Y,D	GB-A-2 121 690 (INFUSAID CORP.) * Abstract; figure 2 * & US-A-4 496 343 ---	11			
A	US-A-4 634 351 (LEONARD et al.) * Whole document *	3-7			
A,D	FR-A-2 305 197 (SIEMENS AG) * Page 8, lines 15-38; figures 1,6 * & US-A-4 077 405 -----	1,9	TECHNICAL FIELDS SEARCHED (Int. Cl.5) A 61 M F 04 B G 01 F		
The present search report has been drawn up for all claims					
Place of search	Date of completion of the search	Examiner			
THE HAGUE	05-07-1989	CLARKSON P. M.			
CATEGORY OF CITED DOCUMENTS					
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document					
T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document					